Commission Implementing Regulation (EU) 2020/2101 of 15 December 2020 renewing the approval of the active substance kieselgur (diatomaceous earth) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2101

of 15 December 2020

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2008/127/EC[(2)] included kieselgur (diatomaceous earth) as an active substance in Annex I to Council Directive 91/414/EEC[(3)].

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(4)].

(3) The approval of the active substance kieselgur (diatomaceous earth), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2021.

(4) An application for the renewal of the approval of the active substance kieselgur (diatomaceous earth) was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 22 February 2019.

(7) The Authority made the supplementary summary dossier available to the public. The Authority communicated the draft renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 27 February 2020, the Authority communicated to the Commission its conclusion[(6)] on whether kieselgur (diatomaceous earth) can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial renewal report and the draft Regulation for kieselgur (diatomaceous earth) to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020 and 16 July 2020, respectively.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[(7)], the Authority concluded that kieselgur (diatomaceous earth) does not meet these criteria. Therefore the Commission concludes that kieselgur (diatomaceous earth) is not to be considered as having endocrine disrupting properties.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance kieselgur (diatomaceous earth) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) The risk assessment for the renewal of the approval of the active substance kieselgur (diatomaceous earth) is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing kieselgur (diatomaceous earth) may be authorised.

(13) It is therefore appropriate to renew the approval of kieselgur (diatomaceous earth).

(14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.

(15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(16) Commission Implementing Regulation (EU) 2020/1160[(8)] extended the approval period of kieselgur (diatomaceous earth) to 31 August 2021 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal of the approval is being taken

ahead of the expiry of that extended approval period, this Regulation shall apply from 1 February 2021.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance kieselgur (diatomaceous earth) is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 February 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2101. (See end of Document for details)*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Kieselgur (Diatomaceous earth) CAS No *61790-53-2* CIPAC No 647	No IUPAC name exists for kieselgur Other synonyms: Diatomaceous earth Diatomite	1 000 g/kg Minimum content of amorphous silica of 800 g/kg The following impurity must not be exceeded in the technical material: Crystalline silica with particle size *below 10 µm – maximum of 1 g/kg*	1 February 2021	31 January 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on kieselgur (diatomaceous earth), and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment, in particular respiratory protective equipment, and other risk

a Further details on the identity and the specification of the active substance are provided in the renewal report.

b Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).

					mitigation measures, where appropriate. Only indoor use is permitted. Member States shall assess any extension of the use pattern beyond use in closed storage environments, in order to establish whether the proposed extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Commission Regulation (EU) No 546/2011[b]. Conditions of use shall include risk mitigation measures, where appropriate.

a Further details on the identity and the specification of the active substance are provided in the renewal report.

b Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).